



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

OCT 5 2004

Stephen G. Juelsgaard  
Genentech, Inc.  
1 DNA Way  
San Francisco, CA 94080-4990

Re: Docket No. 2004P-0171/CP1

Dear Mr. Juelsgaard:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated April 8, 2004. Your petition requests that FDA:

- (1) Refrain from publishing a draft guidance that describes principles for determining the similarity or sameness of biotechnology-derived products,
- (2) Refrain from approving any biotechnology-derived product that is characterized as similar to or the same as a Genentech product based on Agency findings of safety or effectiveness for the Genentech product, and
- (3) Develop a process under which Genentech will be notified of any potential use of its trade secret or confidential commercial data and information and may intervene to stop such use.

FDA has been unable to reach a decision on your petition because it raises significant and complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

2004P-0171

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